

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER

NOTICE TO TAKE VIDEOTAPED ORAL DEPOSITION

TO: **Jessica M. Heinz, Esq,**
CIPRIANI & WERNER, P.C.
450 Sentry Parkway, Suite 200
Blue Bell, Pennsylvania 19422
Attorneys for Defendants Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and
Aurolife Pharma, LLC (hereinafter "Defendants").

Please take notice that pursuant to Federal Rule of Civil Procedure 30, and other applicable Rules, including the Local Civil Rules, and the applicable Orders of the Court, Plaintiffs, by and through their counsel, will take the videotaped deposition of Sanjay Singh, Associate President – North America Operations, on May 19 and 20, 2021, at 9:00 a.m. eastern standard time, and continuing until completion, at Cipriani & Werner, P.C., 450 Sentry Parkway, Suite 200, Blue Bell, Pennsylvania 19422, via zoom, in accordance with the Fact Witness Deposition Protocol, Case Management Order #20, filed November 17, 2020 (Document 632). The deposition shall first address the Federal Rule of Civil Procedure 30(b)(6) topics listed on Exhibit A attached hereto, followed by deposition of the witness in his individual capacity. The witness shall produce the documents requested at Exhibit B, attached hereto, at least five days in advance of the deposition.

Pursuant to the meet and confer between the parties, a translator will not be provided.

TAKING ATTORNEYS FOR PLAINTIFFS:

RUBEN HONIK, ESQ.
Golomb & Honik, P.C.
1835 Market Street #2900
Philadelphia, PA 19103
Telephone: 215-278-4449
Fax: 973-228-0303
ruben@honiklaw.com

Daniel Nigh
Levin Papantonio Rafferty Proctor Buchanan O'Brien Barr Mougey P.A.
316 South Baylen St.
Pensacola, FL 32502
Telephone: (850) 435-7013
E-Mail: dnigh@levinlaw.com

The videotaped deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure.

February 23, 2021

BURSOR & FISHER, P.A.

By: /s/ Andrew J. Obergfell
Andrew J. Obergfell

Joseph I. Marchese
Andrew J. Obergfell
888 Seventh Avenue
New York, NY 10019
Telephone: (646) 837-7150
Facsimile: (212) 989-9163
Email: aobergfell@bursor.com
jmarshese@bursor.com

EXHIBIT A

30(B)(6) TOPICS

Nitrosamine Contamination

1. The cause of the contamination of Aurobindo's valsartan API with nitrosamines, including, but not limited to, NDMA and NDEA.
2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the Aurobindo API.
3. Any assessment or root cause analysis conducted by Lantech Pharmaceuticals with regards to NDMA and NDEA contamination in recycled or recovered solvents.

Testing

4. The testing performed by Aurobindo or its agents, to evaluate the purity and contents of Aurobindo's API.
5. The testing performed by any entity or person other than Aurobindo or its agents but known to Aurobindo, to evaluate the purity and contents of Aurobindo's valsartan API.
6. The testing performed by Aurobindo or its agents, to evaluate the purity and contents of Aurobindo's finished dose.
7. The testing performed by Aurobindo or its agents to evaluate the purity and contents of recovered or recycled solvents provided by Lantech Pharmaceuticals.
8. The testing performed by any entity or person other than Aurobindo or its agents but known to Aurobindo, to evaluate the purity and contents of Aurobindo's finished dose.
9. The chromatogram and mass spectrometry results for all testing by Aurobindo or its agents of Aurobindo's valsartan API.
10. The chromatogram and mass spectrometry results for all testing by any entity or person other than Aurobindo or its agents but known to Aurobindo, of Aurobindo's valsartan API.
11. The chromatogram and mass spectrometry or other results for all testing by Aurobindo or its agents of Aurobindo's finished dose.
12. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Aurobindo or its agents but known to Aurobindo, of Aurobindo's finished dose.
13. Aurobindo's evaluation of the potential risks to the purity or contents of Aurobindo's API posed or caused by solvents used during the manufacturing process.

14. The chromatogram and mass spectrometry results for all testing by Aurobindo or its agents of the solvents utilized in the manufacture of Aurobindo's valsartan API.
15. The chromatogram and mass spectrometry results for all testing by any entity or person other than Aurobindo or its agents but known to Aurobindo, of the solvents utilized in the manufacture of Aurobindo's API.
16. The extent of the actual and potential nitrosamine contamination of Aurobindo's valsartan API and valsartan finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

Quality Assurance and Quality Control Activities

17. Aurobindo's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Aurobindo's valsartan API. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
18. Aurobindo's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Aurobindo's valsartan finished dose. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
19. Aurobindo's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Aurobindo's valsartan API. (The parties to meet and confer to identify the relevant cGMP's.)
20. Aurobindo's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Aurobindo's valsartan finished dose. (The parties to meet and confer to identify the relevant cGMP's.)
21. Aurobindo's SOPs/policies/procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with procurement of recovered or recycled solvents, and selection of vendors to provide such services. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)

Process Development

22. The development of each Drug Master File, including any risk assessments conducted on starting materials, or solvents, for Aurobindo's valsartan API.
23. The use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Aurobindo's valsartan API, including: (1) the reasons for each, and any modifications, (2) the testing and evaluation in connection with each, including any modification, and (3) the relationship between each, including any modifications, and the nitrosamine contamination of Aurobindo's valsartan API.
24. Any evaluation conducted by or on behalf of Aurobindo with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, and in particular potential nitrosamine impurities, in the manufacturing process for Aurobindo's valsartan API.
25. Aurobindo's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for Aurobindo's valsartan API.
26. Aurobindo's evaluation and knowledge of the risks of using recovered or recycled solvents in the manufacture of Aurobindo's API and finished dose.
27. Aurobindo's evaluation and knowledge of the health risks of exposure to nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Aurobindo's valsartan API.
28. Aurobindo's evaluation and knowledge of the health risks of exposure to nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Aurobindo's valsartan finished dose.

Communications with Regulatory Agencies

29. The communications with any regulatory authority, including but not limited to the FDA, with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Aurobindo's valsartan API.
30. Aurobindo's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Aurobindo's valsartan API with nitrosamines including NDMA and NDEA.
31. Aurobindo's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Aurobindo's valsartan finished dose with nitrosamines including NDMA and NDEA.
32. Aurobindo's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for Aurobindo's Valsartan API Drug Master Filings.

Compliance with cGMPs

40. Aurobindo's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of Aurobindo's API and finished dose. (The parties to meet and confer to identify the relevant cGMP's.)
41. The policies, practices, procedures and trainings for monitoring compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in the manufacture of Aurobindo's valsartan API and valsartan finished dose. (The parties to meet and confer to identify the relevant cGMP's.)
42. The policies, practices, procedures and trainings intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, for monitoring material providers (such as Lantech Pharmaceuticals) and their compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents,. (The parties to meet and confer to identify the relevant cGMP's.)

EXHIBIT B

DOCUMENT REQUESTS

1. The most recent resume/Curriculum Vitae and LinkedIn profile for Sanjay Singh.
2. The complete production of Sanjay Singh's relevant custodial documents, including those maintained on personal computers or electronic devices, to the extent not produced prior.

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CERTIFICATE OF SERVICE

I hereby certify that on February 23, 2021, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

BURSOR & FISHER, P.A.

By: /s/ Andrew J. Obergfell
Andrew J. Obergfell

Joseph I. Marchese
Andrew J. Obergfell
888 Seventh Avenue
New York, NY 10019
Telephone: (646) 837-7150
Facsimile: (212) 989-9163
Email: aobergfell@bursor.com
jmarchese@bursor.com